REMARKS

Prior to entry of the present amendment, claims 1-10 are pending. Claims 7-10, due to a Restriction Requirement, are withdrawn from consideration. Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph. Claims 1 and 5 are rejected under 35 U.S.C. § 102. Applicants address each basis for rejection as follows.

Claim amendments

Claims 1 and 2 have been amended, claims 3-10 have been cancelled, and new claims 11 and 12 have been added.

In particular, claim 1 has been amended to recite the term "intracerebrally." This amendment finds support, for instance, in Examples 2 and 3 of the application as filed. In addition, claim 1 now recites that the treatment is administered to a subject having "a brain tumor." This amendment finds support, for example, in original claim 5. Further, claim 1 as amended now recites a Sendai virus vector which encodes interleukin-2. Support for this amendment is found, for example, at page 12, lines 15-19, of the English language specification and in original claim 6. Claim 2 has been amended to incorporate the features of claims 3 and 4.

New claims 11 and 12 recite a Sendai virus vector lacking both M and F genes. Support for these claims is found, for example, at page 4, lines 19-20, page 15, lines 29-31, page 27, lines 1-5, and in Figure 1 of the English language specification.

No new matter has been added by the present amendments. Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-6 are rejected under 35 U.S.C. § 112 for an asserted lack of enablement in the specification. Claims 3-6 have been canceled and the rejection of these claims, therefore, is moot. The Office states (page 2):

> [T]he specification, while being enabling for a method of treating a brain tumor comprising intracerebrally administering a Sendai viral vector (SeVV) lacking both the M and F genes to a mammal having a brain tumor, wherein the SeVV encodes IL-2 operably linked to a promoter, does not reasonably provide enablement for treating any tumor using any minus-strand RNA viral vector encoding any cytokine.

While Applicants disagree with the Office's assertion regarding the scope of enablement, claim 1, in general, has been amended to be directed to subject matter that the Office has indicated to be enabled by the specification. Applicants note that claim 1, as amended, does not require the Sendai virus vector to lack both the M and F genes. (This feature is recited in new claims 11 and 12).

Applicants respectfully submit that use, in the claimed methods, of Sendai virus vectors other than a vector lacking both the M and F genes is also enabled by the specification as filed in view of the knowledge in the art at the time of filing. In particular, the specification states (page 15, lines 29-36):

> [A] minus-strand RNA virus of the invention may be deficient in any of the wild type genes. For example, a viral vector in which the M, F, or HN gene, or any combination thereof is inactivated of deleted, can be preferably used in this invention. Such viruses can be reconstituted, for example, by externally supplying the products of the deficient genes. Similar to wild type viruses, the viruses thus prepared adhere to host cells and cause cell fusion, but they cannot form daughter virions that retain the same infectivity as the original vector ... Therefore, such vectors are useful as safe viral vectors that can only introduce genes once.

Applicants also direct the Office's attention to three references, Suzuki et al. (Eur. J. Neurosci. 13: 2299-2308, 2001; "Suzuki"), Shirakura, M. et al. (Exp. Anim. 52: 119-127, 2003; "Shirakura"), and Li et al. (J. Virol. 74: 6564-6569, 2000; "Li"), copies of which are enclosed herewith.

As evidenced by the title and the abstract, Suzuki demonstrated that a wild-type Sendai virus vector having both the M and F genes is suitable as a gene delivery vehicle

to brain. Use of this vector resulted in successful control of feeding behavior of rats. In addition, Shirakura shows that the wild-type Sendai virus vector is useful for gene therapy for stroke (see last sentence of the abstract). Further, Li teaches that a Sendai virus vector lacking the F gene is also suitable for gene delivery to brain (see Fig. 6). Accordingly, Applicants submit that, at the time of filing, Sendai virus vectors other than vectors lacking both the M and F genes were also known to be suitable for gene delivery to brain. As such, at the time of filing, one skilled in the art would reasonably have expected that Sendai virus vectors other than ones lacking both the M and F genes could be used in the claimed methods without undue experimentation.

In addition, claim 2 has been amended to be directed to "subcutaneously administering tumor cells that have lost their growth ability" in accordance with the Examiner's suggestion.

For all the above reasons, Applicants submit that the claims as amended meet the enablement requirement of 35 U.S.C. § 112, first paragraph. The enablement rejection may be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Kai (U.S. Patent No. 6,514,728; "Kai"), and claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bitzer (J. Gene Medicine 5:543-553, 2003; "Bitzer"). Applicants address these rejections, in turn, below.

Kai

The Office states (page 6):

> Kai administered a Sendai [virus] vector encoding INF-gamma to treat tumors (Example 1, paragraph bridging col. 5 and 6).

Applicants note that claim 1, as amended, requires administering a Sendai virus

vector encoding "interleukin-2." Kai fails to describe this feature of the claimed invention and, therefore, cannot anticipate claim 1, as amended, or its dependent claims. The anticipation rejection over Kai may be withdrawn.

For the record, Applicants respectfully disagree with the Office's characterization of Kai. Kai does not teach *in vivo* administration of a Sendai virus vector, but rather teaches a "mass expression system" using hen's eggs infected with a Sendai virus vector to produce canine IFN-γ (interferon- γ) protein (see col. 2, lines 56-65).

Bitzer

The Office states (page 6):

> The phrase "anti-tumor treatment" is an intended use and does not bear patentable weight because it does not alter the steps of the method which are limited to administering a minus strand RNA viral vector. The claim does not require administering the vector to a patient having a tumor. Claim 5 is included because it limits "the tumor" of claim 1, however, claim 1 does not require administering the vector to a patient with a tumor.

As stated above, claim 1 as amended requires administering a Sendai virus vector encoding "interleukin-2" to a subject having a "brain tumor." These features are not described by Bitzer. Applicants respectfully submit that claim 1 as amended is free of the anticipation rejection over Bitzer. Claim 5 has been cancelled and rejection of this claim is moot. The anticipation rejection over Bitzer should also be withdrawn.

Information Disclosure Statement

Applicants note that, on the Forms PTO-1449 returned with the current Office Action, several references were apparently not considered by the Examiner. In particular, a line was drawn through the International Search Report for PCT/JP2005/000238 listed on the Form PTO-1449 filed with the March 27, 2007 Information Disclosure Statement ("IDS") and a line was drawn through the Supplemental European Search Report for EP

05 70 3477 listed on the Form PTO-1449 filed with the April 5, 2007 IDS. Applicants respectfully request consideration of these references.

Nonetheless, Applicants herewith resubmit the International Search Report for PCT/JP2005/000238 and the Supplemental European Search Report for EP 05 70 3477 with an IDS. Should the Office continue to object to these references, Applicants respectfully request that the Office provide its reason for doing so.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

Enclosed are a Petition to extend the period for replying to the Office Action for two (2) months, to and including August 6, 2008, and an authorization to charge the required extension fee to Deposit Account No. 03-2095. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 25 July 2008

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